



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Use of a Single Institutional Review Board for Cooperative Research Draft

Guidance

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document entitled, “Use of a Single Institutional Review Board for Cooperative Research Draft.”

DATES: Submit written comments by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit written requests for a single copy of the draft guidance document entitled “Use of a Single Institutional Review Board for Cooperative Research Draft Guidance,” to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-453-8420. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft guidance documents.

You may submit comments identified by docket ID number HHS-OASH-2022-0011 (Use of a Single Institutional Review Board for Cooperative Research Draft Guidance), by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Enter the docket ID number and click on “Search.” On the next page, click the “Comment Now” action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:* Natalie Klein, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Natalie Klein, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; e-mail address: Natalie.klein@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP is announcing the availability of a draft guidance document for public comment titled “Use of a Single Institutional Review Board for Cooperative Research.” The document is intended primarily for institutions, institutional review boards (IRBs), investigators, institutional officials, and other human research protection staff.

The draft guidance document applies to activities that are conducted or supported by HHS. It is intended primarily to help entities implement the

requirement for use of a single IRB for cooperative research (subpart A of 45 CFR part 46.114). In particular, the draft guidance addresses the following topics:

- (1) What is cooperative research?
- (2) When must an institution rely on a single IRB for approval of cooperative research?
- (3) Who decides which IRB will be the IRB of record for the purposes of regulatory compliance?
- (4) Can an institution that is not required to comply with 45 CFR 46.114(b)(1) for a particular study still choose to rely on a single IRB for review of cooperative research?
- (5) Can an institution involved in cooperative research choose to conduct its own IRB review of the research even though review is required by a single IRB that is located elsewhere?
- (6) Are there documentation requirements for use of a single IRB in cooperative research?
- (7) What are some of the operational capacities an IRB should have in order to serve as a single IRB?
- (8) What are the responsibilities of the reviewing IRB with respect to information pertaining to sensitivity to community attitudes and the local context for proposed research?
- (9) What are the responsibilities of the reviewing IRB pertaining to applicable State and local laws?

II. Electronic Access

Persons with access may obtain the draft guidance documents on OHRP's website at <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html>.

Jerry Menikoff,

Director,

Office for Human Research Protections.